# TATENT COOPERATION TREE JY

# From the INTERNATIONAL BUREAU **PCT NOTIFICATION OF ELECTION Assistant Commissioner for Patents** United States Patent and Trademark (PCT Rule 61.2) Office **Box PCT** Washington, D.C.20231 **ETATS-UNIS D'AMERIQUE** Date of mailing (day/month/year) in its capacity as elected Office 07 April 2000 (07.04.00) Applicant's or agent's file reference International application No. **DEX-0039** PCT/US99/16357 Priority date (day/month/year) International filing date (day/month/year) 04 August 1998 (04.08.98) 20 July 1999 (20.07.99) **Applicant** SUN, Yongming et al 1. The designated Office is hereby notified of its election made: in the demand filed with the International Preliminary Examining Authority on: 29 February 2000 (29.02.00) in a notice effecting later election filed with the International Bureau on: 2. The election was not made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

Pascal Piriou

Telephone No.: (41-22) 338.83.38

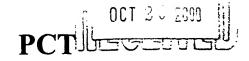


#### From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JANE MASSEY LICATA LAW OFFICES OF JANE MASSEY LICATA 66 E. MAIN STREET MARLTON NJ 08053

Docket System Status Report Docket Book

1119 = 2.4-01



### NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

(PCT Rule 71.1)

Date of Mailing (day/month/year)

170CT 2000

Applicant's or agent's file reference

**DEX-0039** 

International filing date (day/month/year)

Priority Date (day/month/year)

PCT/US99/16357

International application No.

20 JULY 1999

04 AUGUST 1998

IMPORTANT NOTIFICATION

Applicant

**DIADEXUS LLC** 

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the 1. international preliminary examination report and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication 2. to all the elected Offices.
- Where required by any of the elected Offices, the International Bureau will prepare an English translation of 3 the report (but not of any annexes) and will transmit such translation to those Offices.

#### REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Commissioner of Patents and Trademarks

Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized office

Telephone No. (703) 308-0196

Form PCT/IPEA/416 (July 1992) \*

### **PCT**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference DEX-0039	FOR FURTHER ACTION	Preliminary	ication of Transmittal of International Examination Report (Form PCT/IPEA/416)
International application No.	International filing date (day)	/month/year)	Priority date (day/month/year)
PCT/US99/16357	20 JULY 1999		04 AUGUST 1998
International Patent Classification (IPC) Please See Supplemental Sheet.	or national classification and	IPC	
Applicant DIADEXUS LLC			
Examining Authority and is	transmitted to the applican	s been prepa t according to	red by this International Preliminary Article 36.
2. This REPORT consists of a	total of sheets.		
This report is also accombeen amended and are the (see Rule 70.16 and Sec	npanied by ANNEXES, i.e., she basis for this report and/or stion 607 of the Administrative	sheets containii	cription, claims and/or drawings which have ng rectifications made before this Authority. under the PCT).
These annexes consist of a to	otal of sheets.		
3. This report contains indication	ns relating to the following	items:	
I X Basis of the repo	ort		
II Priority			
·	nt of report with regard to	novelty, inven	tive step or industrial applicability
IV X Lack of unity of		•	
V X Reasoned stateme		egard to novel	ty, inventive step or industrial applicability;
VI Certain documents			
	the international application		
<b>.</b> ≒	ns on the international applic	ation	
	••		
Date of submission of the demand	D	ate of completion	on of this report
29 FEBRUARY 2000		02 OCTOBE	
Name and mailing address of the IPEA		uthorized office	M. (.10
Commissioner of Patents and Trade Box PCT Washington, D.C. 20231	marks	SUSAN UNC	GAR POLL FOR
Facsimile No. (703) 305-3230	Te	elephone No.	(703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998)\*

International application No.

PCT/US99/16357

Basis of the	report		
With regard to th	ne elements of the intern	national application:*	
	ational application a		
프			
pages	·		, as originally filed
pages	NONE		, filed with the demand
pages	NONE	, filed with the letter of	
_			
X the claim	~~ ~ .		as originally filed
pages		, as amended (together with	any statement) under Article 19
pages		, as amended (together with	, filed with the demand
pages pages		, filed with the letter of	
pages			
X the draw	ings:		
pages _			, as originally filed
pages	NONE	·	, filed with the demand
pages		, filed with the letter of	
X the seque	ence listing part of the	e description:	as originally filed
pages _	NONE		, filed with the demand
pages pages		, filed with the letter of	
the internation	al application was file	ements marked above were available or furnished to a duriless otherwise indicated under this item. nished to this Authority in the following language	which
		of the international application (under Rule 48. furnished for the purposes of international prelimina	
or 55.3).  With regard (	to any nucleotide and examination was carr	d/or amino acid sequence disclosed in the intermined out on the basis of the sequence listing:	ational application, the internatio
		al application in printed form.	•
		national application in computer readable form	
		is Authority in written form.	
		is Authority in computer readable form.	
The state	ement that the subsect	mently furnished written sequence listing does no	ot go beyond the disclosure in th
The state been fun	ement that the informa	led has been furnished.  tion recorded in computer readable form is identica	I to the writen sequence listing ha
		lted in the cancellation of:	
		NONE	
<b>ਜ਼</b> ‴	ne description, pages	NONE	
	ne claims, Nos.		
	ne drawings, sheets	1.6	nce they have been considered to
5. X This rep	ort has been drawn as	if (some of) the amendments had not been made, si	)) **
		L as indicated in the Supplemental Box (Rule 70.2(c) furnished to the receiving Office in response to an invand are not annexed to this report since they do to	
and 70 (7)			
in this report	t as "originally filed	such amendments must be referred to under item	

International	application	No

INTERNATIONAL PRELIMINARY EXAMINATION	ON REPORT	PCT/US99/16357	
IV. Lack of unity of invention			
1. In response to the invitation to restrict or pay addit	ional fees the applican	nt has:	
x restricted the claims.			
paid additional fees.			
paid additional fees under protest.			
neither restricted nor paid additional fees.			
2. This Authority found that the requirement of uni not to invite the applicant to restrict or pay addit	ity of invention is not c tional fees.	complied with and chose, according to Rule	68.1,
3. This Authority considers that the requirement of unity of in	nvention in accordance v	with Rules 13.1, 13.2 and 13.3 is	l
complied with.			
x not complied with for the following reasons:			
Please See Supplemental Sheet.			
•			
		:	
		•	
Consequently, the following parts of the international as in establishing this report:	pplication were the subj	ect of international preliminary examination	
all parts.			
the parts relating to claims Nos.			

International application No. PCT/US99/16357

citations and explanations supporting	such statem		
statement			
Novelty (N)	Claims	6	YE
		1, 2	
Inventive Step (IS)	Claims	6	YE
inventive step (15)		1,2	
	Clums	-1-	
Industrial Applicability (IA)	Claims	1, 2, 6	YE
moustrial Applications (1A)		NONE	
citations and explanations (Rule			<del></del>
Claims 1 and 2 lack novelty under PCT Art  The claims are drawn to a method for diagnos the levels of colon specific genes in the cell	sing the presence	of colon cancer, metastatic colon cancer in	a patient by measuring
24-42).  Claim 6 meets the criteria set out in PCT A method wherein the CSG is SEQ ID NO:1,	rticle 33(2)-(4),	because the prior art does not teach or fa	irly suggest the claim
NEW CITATIONS			
NONE			
NEW CITATIONS			

International application No.

PCT/US99/16357

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

#### **CLASSIFICATION:**

The International Patent Classification (IPC) and/or the National classification are as listed below: IPC(7): A61K 51/00, 39/395; C12Q 1/00,1/68; G01N 33/53; C07K 1/00, 16/00 and US Cl.: 424/1.49, 130.1, 141.1, 178.1; 435/4, 6, 7.1; 530/350, 387.1, 387.9, 388.1, 388.8, 389.7, 391.1, 391.3, 391

#### I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed: NONE

#### IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

As applicant was previously notified this International Preliminary Examining Authority has found plural inventions claimed in the International Application covered by the claims indicated below:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1, 2 and 6, drawn to a method for diagnosing the presence of colon cancer in a patient.

Group II, claim(s) 3 and 6, drawn to a method of staging colon cancer in a patient.

Group III, claim(s) 4,5,6, drawn to a method of monitoring colon cancer in a patient.

Group IV, claim(s)7, drawn to an antibody against CSG.

Group V, claim(s) 8-9, drawn to a method of treating colon cancer in a patient.

Group VI, claim(s) 10-11, drawn to a method of treating colon cancer in a patient.

and it considers that the International Application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below:

The inventions listed as Groups I-VI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VI appears to be that they all relate to CSG which is a colon specific gene.

However, US Patent No. 5,733,748 specifically teaches colon specific genes and polypeptides encoded by those genes as well as method of diagnosing colon cancer by measuring the gene products and antibodies specific to the colon specific gene products (see abstract).

Therefore the technical feature linking the inventions of Groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a method for diagnosing the presence of colon cancer in a patient.

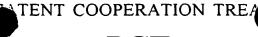
The special technical feature of Group II is considered to be a method of staging colon cancer in a patient.

The special technical feature of Group III is considered to be a method of monitoring colon cancer in a patient.

The special technical feature of Group IV is considered to be an antibody against CSG.

The special technical feature of Group V is considered to be a method of imaging colon cancer in a patient.

The special technical feature of Group VI is considered to be a method of treating colon cancer.





### INTERNATIONAL PRELIMINARY EXAMINATION REPOR

REC'D 2 0 OCT 2000
WIPO PCT

(PCT Article 36 and Rule 70)

DEX-0039	FOR FURTHER ACTION	Preliminary Examination Report (Form PCT/IPEA/416)		
International application No.	International filing date (day/n	month/year) Priority date (day/month/year)		
PCT/US99/16357	20 JULY 1999	04 AUGUST 1998		
International Patent Classification (IPC) Please See Supplemental Sheet.	or national classification and IP	PC		
Applicant DIADEXUS LLC				
	ary examination report has transmitted to the applicant	been prepared by this International Preliminary according to Article 36.		
2. This REPORT consists of a	total of sheets.			
been amended and are the	e basis for this report and/or she tion 607 of the Administrative	ets of the description, claims and/or drawings which have leets containing rectifications made before this Authority. Instructions under the PCT).		
3. This report contains indication	<u> </u>	tems:		
I Basis of the repor		Const.		
II Priority				
		les in continue agent on industrial agenticated in		
	-	ovelty, inventive step or industrial applicability		
IV X Lack of unity of				
	nations supporting such statem	and to novelty, inventive step or industrial applicability; nent		
VI Certain documents	cited			
VII Certain defects in the	he international application			
VIII Certain observation	s on the international applicati	ion		
Details of a basical and the desired	n	of completion of this report		
Date of submission of the demand	Date	of completion of this report		
29 FEBRUARY 2000	0	22 OCTOBER 2000		
Name and mailing address of the IPEA/		orized offices 10		
Commissioner of Patents and Tradem Box PCT Washington, D.C. 20231		SUSAN UNGAR		
Facsimile No. (703) 305-3230	Telep	phone No. (703) 308-0196		

I.	Basis	f the	rep rt				
1 11	Vish	and to the	e elements of the interna	ational application	on:*		
_	<b>-</b> ¬ . ັ		e elements of the interna ational application as				
<u> </u>	≌			Oliginally II	100		
L	A	descri					, as originally filed
	pag	ges					, filed with the demand
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	pa	ges		<del></del>	,		
Г	X the	claims	<b>s</b> :				
L		ges	32-34				, as originally filed
	pag	ges	NONE		, as amended (	together with any sta	tement) under Article 19
	pa	ges	NONE				, filed with the demand
	pa	ges	NONE	, filed v	vith the letter of _		
_	<b>-</b>						
L		drawi:	MONE				, as originally filed
	-	ges		<del>"</del>			, filed with the demand
		ges ges			filed with the	letter of	<u> </u>
	Pa	Bc., —			, ,	<del></del>	
Γ	X the	seque	nce listing part of the	description:			
	pa,	ges	NONE				, as originally filed
	na	ges	NONE				, filed with the demand
	pa	ges	NONE		, filed with the	letter of	
	the inte These e the the	mationa elements langua e langua	al application was filed, were available or furnis wage of a translation fundage of publication of	unless otherwished to this Au urnished for the	ise indicated under the authority in the following the purposes of incomal application (to a purpose in the pur	his item. ing language ternational search (un inder Rule 48.3(b)).	which is:  der Rule 23.1(b)).  ination (under Rules 55.2 and/
3.	With representation	egard to inary e	o any <b>nucleotide and/</b> o xamination was carried	or amino acid	<b>d sequence</b> disclose basis of the sequen	ed in the international accelisting:	application, the international
	] "	ntained	in the international a	application in	n printed form.		
Г			ther with the internat			readable form.	
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[	Th int	ne stater ternation	ment that the subseque nal application as filed	ently furnished I has been fur	d written sequence mished.	listing does not go be	yond the disclosure in the
[	T be	ne staten en furni	nent that the information shed.	n recorded in	computer readable f	form is identical to the	writen sequence listing has
ا ہا	X T	he ame	ndments have resulted	d in the canc	cellation of:		
4.1				MONE			
		<b>=</b> ""	description, pages				
	يإ		claims, Nos.	NONE			
Į			drawings, sheets <del>/fig</del>				
*	Replace in this and 70	peyond tement ship report of 17).	he disclosure as filed, as	s indicated in t rnished to the r d are not ann	the Supplemental Boreceiving Office in reserved to this report	ox (Rule 70.2(c)).** sponse to an invitation wisince they do not conta	have been considered to go ander Article 14 are referred to an amendments (Rules 70.16

IV. Lack of unity of invention	
1. In response to the invitation to restrict or pay additional fees the applicant has:	
X restricted the claims.	
paid additional fees.	
paid additional fees under protest.	
neither restricted nor paid additional fees.	
2. This Authority found that the requirement of unity of invention is not complied with and chose, according to not to invite the applicant to restrict or pay additional fees.	to Rule 68.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is	
complied with.	
X not complied with for the following reasons:	
Please See Supplemental Sheet.	
·	
·	
4. Consequently, the following parts of the international application were the subject of international preliminary examining establishing this report:	nation
all parts.	
the parts relating to claims Nos	

. statement		ent	
	<del></del>		
Novelty (N)	Claims	6	YES
		1, 2	NO
Inventive Step (IS)		6	
	Claims	1,2	NO
V 1 1 A . 1 . 1 . 1 . 2 A A	Claime	1, 2, 6	YES
Industrial Applicability (IA)		NONE	NO
	Ciuinis		
the levels of colon specific genes in the cells US Patent No. 5,733,748 teaches specifically in order to diagnose colon cancer, metastatic (24-42).	teaches methods colon cancer what rticle 33(2)-(4), 2 or 3.	of colon cancer, metastatic colon cancer in a patient by meas atients and comparing this measurement to normal controls of diagnosing colon cancer by measuring the colon specific therein overexpression is indicative of colon cancer (see col. 2, because the prior art does not teach or fairly suggest the colon cancer (see col. 2).	genes Lines

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

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Group VI, claim(s) 10-11, drawn to a method of treating colon cancer in a patient.

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